K031010

JUN 25 2003

510(K) SUMMARY

Submitter of 510(k): SB LUCIUS, INC.

9778 Katella Ave. Ave. Ste 205, Anaheim, CA 92804
Phone: (714) 530-2814, Fax : (714) 530-3448,

Contact person: Dae Kyu Chang
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Date of Summary: March. 26, 2003

Trade name: MIRACLE 98
Common: Dental casting alloy
Classification name: Gold based alloys and precious metal alloys for clinical use
Product code: EJT
Classification: Class II

Legally marketed device: Heraeous Kulzer's Jel Bios Pure
510(k) number: K002645

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS

Test methods applied: as in ANSI/ADA 5 and ISO 9693

Comparison of composition:

COMPOSITION (WEIGHT)

Device Name	Au (%)	Pt (%)	In (%)	Zn (%)
Jel Bios Pure	99.30	<1.0	<1.0	<1.0
Ceranum 98	97.60	2.1	<1.0	<1.0

Comparison of physical and mechanical properties:

Alloy	Melting Point Range (°F)	Hardness (Vickers)	Yield Strength (psi)	Elongation (%)	CTE ($x10^{-6}$/ °C)	Density (g/cm3)
Jel Bios Pure	1,900-2,010	50	55,000	45.0	15.3	19.2
Miracle 98	1,904-2,015	45	54,000	50.0	15.1	19.2

Discussion:

Since the composition of the legally marketed alloy and the new device is very similar, it may be assumed that the biological compatibility of the alloys is also very similar.

Conclusion:

The main elements and their concentration are almost identical.
MIRACLE 98 is a High Noble, Micro-fine, Yellow, Gold based alloy to be used for single unit with lower fusing porcelains and indirect restorative composites. MIRACLE 98 is a high gold ceramic alloy, which heightens the porcelain esthetics of the restoration and provides strength, durability and color of gold. Despite minor differences in the materials, we believe that MIRACLE 98 is a substantially equivalent to Heraeous Kulzer's "el Bios Pure". These changes do not affect safety or effectiveness.

Statement of indication for use: MIRACLE 98 is intended for manufacturing:

- Porcelain to metal fabrication of single units

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 2003

Ms. Dae-Kyu Chang
President
SB Lucius, Incorporated
9778 Katella Avenue, Suite 205
Anaheim, California 92804

Re: K031010
Trade/Device Name: MIRACLE 98
Regulation Number: 872.3060
Regulation Name: Gold-Based Alloys and Precious Metal Alloys for Clinical Use
Regulatory Class: II
Product Code: EJT
Dated: March 26, 2003
Received: March 31, 2003

Dear Ms. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

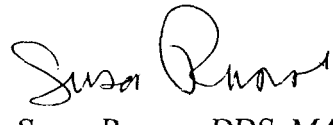
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SB LUCIUS,INC.
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Phone: (714) 530-2814,
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INDICATIONS FOR USE

510(K) Number : K03101C

Device Name(s) : MIRACLE 98

MIRACLE 98 is intended for manufacturing :

- Porcelain to metal fabrication of single units

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CHRD,OFFICE OF DEVICE EVALUATION(OED)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K03101C